

29. (New) The pharmaceutical composition according to claim 2, wherein the bile salt is underivatized or derivatized.

30. (New) The pharmaceutical composition according to claim 29, wherein the underivatized bile salt is selected from the group consisting of cholate, deoxycholate, chenodeoxycholate, and ursodeoxycholate.

31. (New) The pharmaceutical composition according to claim 30, wherein the bile salt is cholate.

32. (New) The pharmaceutical composition according to claim 2, wherein the derivatized bile salt is selected from the group consisting of taurocholate, taurodeoxycholate, tauroursodeoxycholate, taurochenodeoxycholate, glycholate, glycodeoxycholate, glycoursodeoxycholate, glycochenodeoxycholate, taurolithocholate, and glycolithocholate.

33. (New) The pharmaceutical composition according to claim 2, wherein the peptide is selected from the group consisting of insulin, secretin, gastrin, gastrin releasing peptide, glucagon, cholecystokinin (CCK) gastric inhibitory peptide (also known as glucose insulinotropic peptide (GIP)), parathyroid hormone, thyrotropin-releasing hormone, gonadotropin-releasing hormone (also known as luteinizing hormone releasing hormone (LHRH)), corticotropin-releasing hormone, somatostatin, adrenocorticotropic hormone (ACTH), renin, angiotensin I, angiotensin II, atrial natriuretic hormone (ANH), somatomedins, calcitonin, haemoglobin, cytochrome C, horseradish peroxidase, aprotinin, mushroom tyrosinase, erythropoietin, somatotropin (growth hormone), growth hormone releasing hormone, galanin, urokinase, Factor IX (also known as Christmas factor), tissue plasminogen activator, antibodies superoxide dismutase, catalase, peroxidase, ferritin, interferon, Factor VIII, soy bean trypsin inhibitor, GLP1, blood coagulation factors, somatostatin, antidiuretic hormone (ADH), oxytocin, polysaccharides, hirudin, and

glycoproteins, such as follicle stimulating hormone (FSH), lutenizing hormone (LH) inhibin, chorionic gonadotropin (CGT) and thyroid stimulating hormone (TSH), and analogues and fragments of all these, or mixtures of one or more of these.

34. (New) The pharmaceutical composition according to claim 33, wherein the peptide is insulin.

35. (New) The pharmaceutical composition according to claim 33, wherein the somatomedins are selected from the group consisting of IGF1 and IFG2.

36. (New) The pharmaceutical composition according to claim 33, wherein the antibodies are selected from the group consisting of IgG, IgM, IgA, IgD, and IgE.

37. (New) The pharmaceutical composition according to claim 2, wherein the pharmaceutical composition is administered orally.

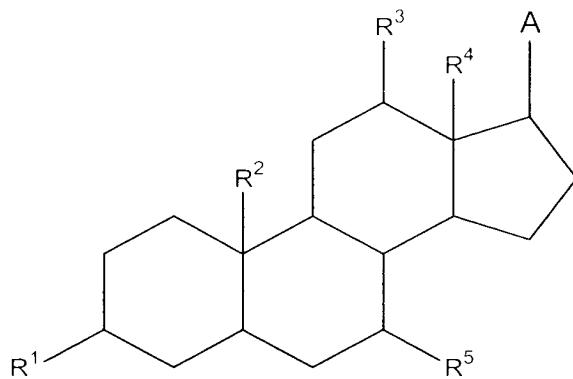
38. (New) The pharmaceutical composition according to claim 37, wherein the pharmaceutical composition comprises a conjugated peptide.

39. (New) The pharmaceutical composition according to claim 2, wherein the pharmaceutical composition is encapsulated to prevent formulation degradation in the stomach.

40. (New) The pharmaceutical composition according to claim 2 for treatment in a subject in need thereof.

41. (New) A method of treating an individual in need thereof comprising orally administering a pharmaceutical composition according to claim 2.

42. (New) A method of making a pharmaceutical composition according to claim 2 comprising, bringing into association an amide of a bile acid/salt of formula (II):



wherein R¹ to R⁵ are each independently OH, H, or C₁₋₆ alkyl; and

A is R⁶-CO-X-Y,

wherein R⁶ is C₂ to C₆ branched or linear alkylene;

X is at least one peptide chain of at least 4 amino acids in length which may be linear, branched or comprise two or more cross-linked polypeptide chains; and

Y is OH, NH₂, or a C₁-C₆ ester group bonded to the terminal carboxy of the polypeptide chain, and

a pharmaceutically acceptable carrier therefor.

Election of Claims

In the Office Action, pending claims 1-23 have been restricted as follows.

Group I: Claims 1, 3-14, and 15-18, drawn to a compound of an amide bile acid/salt bound to a peptide, etc. of Formula I, and a composition containing the compound, classified in class 530, subclass 300+ (peptides of 3 to 100 amino acid residues), 345 (chemical aftertreatment); class 514, subclass 2+ (composition containing peptide); class 552, subclass 548-551 (various bile acids/salts).

Group II: Claim 2, drawn to a compound of Formula II, classified in class 530, subclass 300+, 345; class 552, subclass 548-551; class 436, subclass 142 (R6-alkylene substitution).

Group III: Claim 19, drawn to a process of making a composition comprising a compound (Invention I), classified in class 514, subclass 2; class 552, subclass 548-551.

Group IV: Claim 20, drawn to a process of use of a composition comprising a compound (Invention I), classified in class 514, subclass 2+; class 552, subclass 548-551.

Group V: Claims 21-23, drawn to a compound (Formula III), classified in class 552, subclass 548-551; class 436, subclass 142; class 514+ (depending on which of the 40 pharmaceutically active agents claimed is attached).

Group VI: Claims 21-23, drawn to a process of making a compound (Formula III) or composition of the compound, classified in class 552, subclass 548-551; class 436, subclass 142; class 514+ (depending on which of the 40 pharmaceutically active agents claimed is attached).

Election of Species

In the Action, a species election is required should Invention I or Invention V or VI be elected for examination on the merits. More specifically, the Action states the following:

As to Invention I, a species would need to be elected from the following two subsets directed to the amide of a bile acid/salt containing a peptide of Formula I:

- A. Underivatised bile salt: one of the fourteen different salt species in claims 9-11; and
- B. Peptide: one of the forty-seven different peptide species of claim 12.